K010061

MAR 1 4 2001

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: March 9, 2001

Name of Product: Dade Behring Dimension® **X**pand™ clinical chemistry system

FDA Classification Name: Discrete photometric chemistry analyzer for clinical use

Predicate Device: Dade Behring Dimension® RxL clinical chemistry system

Device Description: The Dade Behring Dimension® **X**pand™ system is a floor model, microprocessor-controlled, integrated instrument that uses prepackaged Dade Behring Flex® reagent test cartridges to measure a variety of analytes in human body fluids.

Intended Use: The Dade Behring Dimension® **X**pand™ clinical chemistry system is an *in vitro* diagnostic device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, mixing, heating, and measuring color intensity to determine a variety of analytes in human body fluids. In addition, the Xpand™ system includes *in vitro* diagnostic test methods for sodium (Na), Potassium (K) and Chloride (Cl) with the following indications for use:
Sodium - Measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the

hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
Potassium - Measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions, characterized by low or high blood potassium levels.
Chloride - Measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Comparison to Predicate Device:

Both the Dimension® Xpand™ and the predicate device (Dimension® RxL) employ the same sample reaction and analyses temperatures and times. This permits utilization of all current Dade Behring Dimension® Flex® reagent test cartridge methods on both systems.

A comparison of the similarities and differences in the features of these two Dade Behring Dimension® system family members is provided in the following chart:

Feature	Dimension® Xpand™	Dimension® RxL
System Control	Microprocessor	Microprocessor
Analysis Temperature	37° C	37° C
Monochromator	Interference filters; tungsten/halogen source	Interference filters; tungsten/halogen source
Sample Vessels	Sample cups, primary collection tubes	Sample cups, primary collection tubes
Sample level detection	Automatic	Automatic
Urine sample dilution	auto, on-board	auto, on-board
Sampler Arm(s)	Single	Dual
Reagent Arms	Dual	Dual

Photometric throughput (typical methods mix)	~ 250 tests/hr	~ 500 tests/hr
Immunoassay capability	Yes	Yes
HM Reaction Vessel Loading	Manual, with dispenser-type feeder	Automatic, with hopper-type feeder

Comments on Substantial Equivalence:

Both Dimension® systems utilize Dade Behring pre-packaged Flex® reagent test cartridges for photometric analyses and integrated multisensor technology (IMT) for measurement of Na, K, and Cl electrolytes. Method split sample comparisons between the Dimension® **X**pand™ and the Dimension® R**x**L clinical chemistry systems demonstrate acceptable clinical and analytical performance with correlation coefficients that ranged from 0.989 to 1.000. Slopes ranging from 0.94 to 1.05 and precision results were also acceptable. These results show substantial equivalency between the two Dimension® systems.

Conclusion:

The Dimension® **X**pand™ and Dimension® R**x**L clinical chemistry systems are substantially equivalent in principle and performance based on the similarity of system design and method split sample comparisons.

Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: March 9, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 4 2001

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: K010061/A001
Trade Name: Dimension® Xpand™ clinical chemistry system
Regulatory Class: II
Product Code: CEM, CGZ, JGS, JJE
Dated: March 5, 2001
Received: March 7, 2001

Dear Mr. Vaught:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name:

Dimension® Xpand™ clinical chemistry system

Indications for Use:

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010061

Richard M. Vaught
Regulatory Affairs and Compliance Manager
March 9, 2001

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)